

REMARKS

The courtesy extended by Examiner Rodriguez during our telephone conversation of December 11, 2003 is acknowledged with appreciation. During the conversation, the combination of the Schulze and Barry references was discussed. Also possible claim amendments were discussed along with the filing of an RCE.

However, subsequent to the telephone conversation, upon further review of the references and further investigation of the law of obviousness, Applicant respectfully submits that the Examiner's combination of references is improper and contrary to law. Therefore, the current claims are believed patentable and withdrawal of the rejection and allowance of the application is respectfully requested.

The decision of the Court of Appeals for the Federal Circuit in In re Rouffet, 149F.3d 1350, 47 USPQ 2d 1453 (Fed. Cir. 1998) is instructive. The court states

As this court has stated, virtually all inventions are combinations of old elements. Environmental Designs, Ltd. v. Union Oil Co., 713F2d 693, 698, 218 USPQ 865, 870 (Fed Cir. 1983). Therefore an examiner may find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit the examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be an illogical and inappropriate process by which to determine patentability. Sensonics, Inc. v Aerosonic Corp., 81. F3d 1566, 1570, 38 USPQ 2d 16551, 1554 (Fed. Cir. 1996).

The Court of Appeals continued

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness.

The Examiner has failed to show the proper motivation to combine or modify the Schulze and Barry references. The Examiner is using the present invention as a blueprint and reconstructing it from disparate teachings and is therefore ignoring Federal Circuit law. The Federal Circuit "forbids the use of hindsight in selection of references that comprise the case of obviousness" *In re Gorman*, 933 F 2d. 982, 986; 18 USPQ 1885, 1888 (Fed Cir. 1991). "When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. *In re Geiger*, 815 F 2d 686, 688; 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). The Examiner's obviousness rejection of claims 1, 10, 11 and 12 is a clear case of impermissible hindsight reconstruction.

Applicant's invention provides a single catheter that could remove the clotting material on the venous side, the arterial side and then achieve mechanical thrombectomy via a rotating wire. Applicant is avoiding the use of drugs to break up the clots since these drugs are expensive, oftentimes require lengthy hospital procedures and create risks of drug toxicity and bleeding complications. The Examiner also misses the point concerning Applicant's balloons.

With the knowledge of the Applicant's invention, the Examiner is reconstructing from diverse references an apparatus to attempt to meet the requirements of the claim. In so doing, the Examiner is ignoring the express objectives of the references. For example, the objective of the Shulze patent is an improvement of an apparatus for delivery of therapeutic agents. (see column 1, lines 6-7). In view of this express objective, how can the Examiner contend that one would eliminate the therapeutic delivery of agents and substitute a rotating wire for mechanical thrombectomy? If Barry is instead considered the base reference, it must be understood that Barry is intended to provide mechanical treatment of removal of material occluding a vascular lumen instead of balloon angioplasty. In view of this express objective, how could the Examiner contend the Barry would be modified to include the balloons of Schulze, such as an angioplasty balloon?

The Examiner's attention is again directed to law concerning improper combination of references, "**If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.** *In re Ratti*, 270 F.2d. 810, 123 USPQ349 (CCPA 1959); MPEP section 2143.01. A mechanical wire would change the

teachings of Shulze which is concerned with drug delivery. A mechanical wire distal of the balloons would change the teaching of Shulze which is designed to seal the space between balloons for drug injection.

The Examiner also fails to understand the teachings of Barry. In the embodiment referenced by the Examiner, the wire rotates to create a path to enable subsequent ablation by the burr. Thus, the wire by itself is insufficient as Barry requires an ablation burr. If the Examiner chooses to select the rotatable wire of Barry, this would mean that the wire would be used to provide a passage for the Schulze catheter. Such rotatable wire would not create a mechanical thrombectomy as required by the claims.

The Examiner states, "The suggestion to combine the references is that Shulze and Barry devices are for removing deposits within the vessel." The Examiner then states, "However, Shulze is by a drug delivery method, and Barry is by a mechanical method." Applicant submits that rather than showing obviousness, this evidences non-obviousness. There is no motivation to combine the disparate teachings of these references.

The Examiner states that "Shulze also recognizes that in addition to the physical enlargement of flow passageways by mechanical displacement of deposits, modern techniques may include the use of therapeutics medicines." However, this sentence, appearing in column 1, line 22 must be read in view of the preceding paragraph which refers to use of a balloon to compress the deposits against the inner wall of the vessel. This is the type of mechanical displacement Schulze is referring to, not any type of rotational wire.

Further, assuming for the sake of argument, if the Examiner chooses to select the wire of Barry to modify Shulze, the teaching would be to place it distal of both balloons. This would render the proximalmost balloon of Shulze useless since it is designed to help retain the injected therapeutic agent between the balloons. **Modification of a reference such that its purpose and function is no longer applicable is improper.** See e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Such modification is against the teachings of Shulze. Placement of a mechanical wire distal of both balloons, as recited in the claims of the present application, goes against the teachings of Shulze, which requires the obstruction treatment occur between the balloons in a confined space.

Changing the location of the Shulze balloons relative to drug injection runs counter to the teachings and objectives of Shulze. The balloons of Shulze create a space for drug injection; moving the drug injection distal of the balloons would not enclose the drug treatment area but would do the opposite as flow would not be inhibited. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d. 810, 123 USPQ349 (CCPA 1959); MPEP section 2143.01.

The Examiner in our telephone conversation stated that she is considering the Shulze patent as a delivery catheter for the Barry wire. However, if one of ordinary skill would look to Shulze as a delivery for Barry, they would determine that the wire must be between the balloons because in Shulze that is where the obstructing material is treated. They would not place it distal of the balloons as in Applicant's claimed invention.

The Examiner also misinterprets Applicants arguments. The Applicant is not "attacking the references individually" as the Examiner suggests. The Applicant is pointing out that the there is no suggestion for the proposed modifications, such modifications are counter to the teachings of the references, and even if the references were combined as the Examiner suggests, the requirements of the claims would still not be met.

Claim 1

The Examiner cannot ignore the limitation of claim 1 that the wire rotates to break up thrombus in an area distal of the first and second balloons. Thus, not only are Shulze and Barry not combinable, but even if they were combined as the Examiner suggests, the end result would be a wire between two balloons, not distal as required by the claim. Further, Barry at best provides a distal wire to create an entry path, and not break up thrombus. That is, Barry discloses the use of an elliptical atherectomy burr with abrasive material to perform the procedure of breaking up the occlusion, e.g. physically contacting and removing the occluding material. In the embodiment of Figures 16 and 17 of Barry, a rotatable wire is disclosed which is rotatable to "create a path for the burr." Rotation of the burr is still necessary to remove the occluding material. Thus, even assuming arguendo Shulze is modified with the wire of Barry, the wire would not perform the thrombectomy

procedure as required, but rather only "create a path for the burr" to perform the atherectomy procedure.

Claim 10

Claim 10 recites a thrombectomy catheter comprising an elongated catheter having a lumen extending therethrough for passage of a rotatable wire for performing thrombectomy, a first balloon disposed on the exterior of the catheter for expanding a stenosis at a venous junction of a dialysis graft and positioned proximal of a distal tip of the rotatable wire, and at least one other balloon disposed on the exterior of the catheter and proximal of the distal tip of the rotatable wire for clearing a blockage at an arterial junction of a dialysis graft, wherein the wire rotates to break up thrombus to perform the thrombectomy procedure in an area distal of the first and second balloons.

The arguments concerning the combination of Barry and Shulze with regard to claim 1 are applicable to claim 10 as well.

Further, in addition to the recitation of the wire rotating to perform thrombectomy distal of both balloons, the claim requires the first balloon for expanding a stenosis at a venous junction and the other balloon clear a blockage at an arterial junction. Nowhere in either the Barry or Shulze patents are such balloons and function disclosed. In Shulze, the proximalmost balloon blocks fluid passage and is not for clearing a blockage. Barry doesn't even have a balloon, let alone a balloon for clearing a blockage at an arterial junction. Therefore, the combination of Shulze and Barry would not even meet the requirements of claim 10. It should also be pointed out that such functional language was discussed with the Examiner.

Claims 11 and 12

Both claims 11 and 12 recite the wire rotating to perform a thrombectomy procedure distal of both balloons. The arguments concerning the combination of Barry and Shulze with regard to claim 1 are applicable to claim 11 and 12 as well.

In short, the Examiner suggests modifying Shulze's fluid injection device to provide a rotational wire of Barry to mechanically remove the obstruction. This means that the wire of Barry must be placed distal of the balloons, in a position not contemplated by Shulze and in fact contrary to

to the teachings of Schulze. This also means that the wire of Barry must be used to remove the obstruction, rather than just provide a path for the solid obstruction removing ablation burr as taught by Barry. Applicants respectfully submit that this combination is improper and contrary to law, and the claims are patentable over the prior art. Therefore, Applicant respectfully requests the withdrawal of the rejection of independent claims 1, 10, 11 and 12.

Claims 2-4, 6-8, 17, 20, 24 and 25 depend from independent claims 1, 10, 11 or 12 and are therefore believed patentable for at least the same reasons that the independent claims are believed patentable.

With respect to the objection to the drawings under 37 C.F. R. 1.84 (p)(S), the specification has been amended to refer to numerals 22' and 24'. The description of Figure 4 has been amended to change "from" to "form." With respect to the term guidewire, the Examiner's attention is directed to page 8, line 10 where the term guide wire is used, thus proper antecedent basis. Withdrawal of the objection to the drawings and disclosure in light of the foregoing is respectfully requested.

Applicants respectfully submit that this application is now in condition for allowance. Prompt and favorable reconsideration of the present application is respectfully requested. The Examiner is invited to contact the undersigned should the Examiner believe it would expedite prosecution.

Respectfully submitted,

Dated: 12/15/03

By: Neil D. Gershon

Neil D. Gershon
Reg. No. 32,225
Attorney for Applicant

Rex Medical
2023 Summer St.
Suite 2
Stamford, CT. 06905
203 348-0377